Session 87 PD, Pharmaceutical Manufacturer Perspectives on Economic Value

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Presenters:
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Whitney Schwark Pratt, FSA, CERA, MAAA
Why you are here.

Description:

• This session will explore pharmaceutical manufacturer perspectives on economic value and how the health economic and outcomes research and actuarial professions can work together to bridge understandings of economic value between the payer and manufacturer industries.

• These professions are based on similar calculus-based statistical foundations, but often diverge in practice. As these professions find common ground, efficiencies in the health care system can be gained.

Learning Outcomes. At the conclusion of this session, attendees will be able to:

• Understand pharmaceutical manufacturer perspectives on economic value definitions

• Evaluate the comprehensive economic value specific prescription drugs provide relative to their competitors or treatment alternatives

• Develop strategies to optimize the overall economic value of prescription formulary designs
Disclaimer

The views expressed herein represent those of the presenter and do not necessarily represent the views or practices of the presenter’s employer or any other party.

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How value is defined and measured...

...is at the heart of any business model.

Value

• Is comparative, affected by the availability of substitutes and alternatives
• Varies by product/service features
• Varies by customer segment or stakeholder perspective
• Varies by business practices and incentives
• Varies by country, culture
• Is dynamic, ever changing

And is a critical input into the pricing decision, along with other considerations.
Janssen Pricing Considerations

• The product’s value to patients and society

• Patient affordability and accessibility

• Our ability to continue to fund future innovation
Approach to Value of a Medicine

1) Its **impact on patients**, as determined by
   • its clinical profile compared to other treatments
   • the way in which it is delivered to patients (treatment burden)
   • its effect on quality of life, productivity, caregiver burden
   • the importance patients and their families place on improved survival and/or improved functioning
   • the importance of having choice, as treatment response varies

2) Assessed over the **appropriate timeframe**, to fully capture all benefits and risks

3) Economic value includes the impact on both the **health care system AND the broader societal perspective**

4) **Best and most appropriate evidence** available, acknowledging **uncertainty** where it exists
A Classical Economist’s Approach

Assume resource **scarcity**, as with abundance, there is no need to make trade-offs or hard choices.

**Opportunity costs** co-exist with scarcity, as money spent on one thing is not available to spend on another.

**Stated preferences** are those which are expressed, and may represent desired features.

**Revealed preferences** are the observed behaviors present in the marketplace, and more accurately represent actual value to the end-user.

**Health Economics** as a special case due to health insurance, which introduces distortions like of moral hazard, adverse selection, information asymmetry.
How do Health Economists Approach Value?

With a set of tools/approaches to measure and prioritize health benefits and costs in order to make choices to attain the most health for the money, from the perspective of the payor.

Cost-effectiveness analysis (CEA) is based on comparative clinical effectiveness analysis, but the effects are unique for the condition and treatment at hand, and not easily comparable across other conditions or treatments.

Quality-Adjusted Life Year (QALY) metric theoretically standardizes health care gains (Tx effects on health status and survival) across markedly different conditions, treatments and populations in an effort to have a basis for more efficient resource prioritization.
How does one measure a QALY?

Remember those stated preferences?

Survey instruments were developed to measure the impact of treatments on patient-reported health-related quality of life (HRQoL). A general instrument, such as the EQ-5D or SF-6, can be used in various conditions, although there are concerns about their sensitivity or ability to detect change.

Techniques were designed to have people trade-off time in different health states (time-trade off), or trade-off risk of death with a health state (standard gamble). This results in stated preference weights that are attached to the various health-related quality of life improvements achieved.
Understanding QALYs

A quality-adjusted life-year (QALY) attempts to take into account both the quantity and quality of life of a health state or that generated by healthcare interventions. It is the arithmetic product of life expectancy and a measure of the health-related quality of the remaining life-years.

A QALY calculation places a weight on time in different health states.

- A year of perfect health is worth 1, and a year of less than perfect health is worth less than 1
- Death is considered to be equivalent to 0
- However, some health states may be considered worse than death and have negative scores
What are some problems with the QALY approach to value?

- Ethical implications, as in discriminating against the aged (fewer life years remain) or disabled (lower functioning at start)
- Expert, technical approach, not easily communicated or understood, models and calculations can also not be transparent (black box)
- Unease with putting a monetary value on a life year, and withholding access to treatments based on it
- Weights used in calculations from experiments done decades ago, with non-US populations, not representative of current US society
- Revealed preferences are often different
- Lack of notice to consumers of use, lack of public acceptance
- Thresholds difficult to reconcile with ACA’s “No Lifetime Limits”
- Not all health care components are subject to prioritization using this approach
- Does not include many other considerations of value
Other Considerations in Approaches to Value

- Equity
- Work productivity
- Scientific spillovers
- Option value
- Value of knowing
- Caregiver Effects
- Dosing/administration

Adapted from Garrison, 2016
How does one attempt to use a QALY?

Next up, selection of a threshold, as in a maximum willingness to pay for a quality-adjusted life year.

Below the threshold, adopt and pay. Above the threshold, negotiate costs downward, do not cover, or limit use to cases where more value can be identified.

With a low threshold, innovations not adopted or seriously delayed, restricted.
Some relevant history and language

- **Health Technology Assessment (HTA)**
  - Since the 1970s (Milt Weinstein, Harvard)
  - “HTA is a field of scientific research to inform policy and clinical decision making on the introduction and use of health technologies.”
  - Technical approach to determining the incremental economic value of new technology adopted by several English-speaking counties with socialized health care systems
  - Utilizes cost per Quality Adjusted Life Year (QALY) and thresholds to theoretically enable efficient limited resource allocation across vastly different spending choices, however QALYs were outlawed for use by PCORI in the PPACA

- **Value Assessment Frameworks (VAFs)**
  - Language came into widespread use ~3 years ago
    - Popularized by ICER (a 501(c)(3) nongovernmental organization)
    - Gained momentum with Hepatitis C treatment value issue

*What is in a name? That which we call a rose by any other name would smell as sweet...*
Value Assessment Frameworks

• A **structured approach** which seeks to identify, quantify and consider comparative clinical and economic value to help inform better quality and more consistent decision-making

• In the US, a **NGO** phenomenon
  • Not a centralized, gov’t approach

• Approach could be applied broadly (services, programs, procedures, drug, device and diagnostic technology), but in practice **typically applied to new technology**
Comparative clinical performance, *but not economic value*

- **Compendia**
  - Clinical focus, but economic consequences → drug coverage
- **Drug Effectiveness Research Program (DERP)**
  - University of Oregon Health Sciences
  - Multiple state Medicaid programs utilize
- **Systematic Reviews**
- **Meta-analysis of clinical trials**
- **Network Meta-analysis of clinical trials, indirect treatment comparisons**
Value Assessment Frameworks

• Utilizes clinical decision resources as a basis for estimating economic value
• Two VAF types, with some convergence
  – Population-based Policy Decision Making
    • Typically combined with budget impact/actuarial models
    • Clinical pathways, insurance coverage, insurance controls (indication/use, formulary status/tiers, prior authorization, step edits, quantity limits, stopping rules, restricted sites of care or specialists)
    • Efforts made to include patient point of view
  – Individual-based Shared Decision Making (SDM)
    • Typically occurs after the pathway or insurance decision
    • Specific to a clinical treatment decision at hand
    • Unbiased, certified tools - lay out treatment choices, benefits, harms, uncertainties, features, out-of-pocket costs
    • Shared by a patient and his/her provider
What Frameworks Currently Exist?

• **Population-based Policy** Decision-Making
  – Institute for Clinical and Economic Review (ICER) Value Assessment Framework (no limitations)
  – MSK DrugAbacus (oncology)
  – ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures (cardiovascular)

• **Individual-based Shared** Decision-Making
  – ASCO Net Health Benefit (oncology)
  – NCCN Evidence Blocks (oncology)
# Features of Current Frameworks

<table>
<thead>
<tr>
<th></th>
<th>ACA/AHA</th>
<th>ASCO</th>
<th>ICER</th>
<th>Sloan Kettering</th>
<th>NCCN</th>
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<tr>
<td>Clinical benefit</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Toxicity/safety</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Treatment novelty</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condition rarity and condition burden</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Budget impact</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost-effectiveness</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Key Questions in Approaches to Value

- Who is evaluating value, for whom?
  - Highly PERSPECTIVE-dependent
  - Business model, self-interest, job

- What elements are in scope?

- What timeframe is utilized?

- What type of evidence/data is utilized?

- How is all this considered? What is not considered?
  - And what uncertainty exists?
ISSUES with VAFs

- Patient perspective insufficiently incorporated
  - What matters to patients?
- Narrow health care system focus
- Short, inappropriate analytic timeframes
- Typically exclude real-world evidence
- Analytic methods and models not transparent
- Wide disagreement over assumptions
- Can become quickly out of date
- Propensity to conflate budget impact & affordability with value
- Framework outputs complex and difficult to understand
- Different frameworks produce disparate results
Three Sets of Case Studies Suggest Logic and Consistency Challenges with Value Frameworks

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Center for the Evaluation of Value and Risk in Health, Tufts Medical Center, Boston, MA, USA

A B S T R A C T

Objective: To assess the logic and consistency of three prominent value frameworks. Methods: We reviewed the value frameworks from three organizations: the Memorial Sloan Kettering Cancer Center (DrugAbacus), the American Society of Clinical Oncologists, and the Institute for Clinical and Economic Review. For each framework, we developed case studies to explore the degree to which the frameworks have face validity in the sense that they are consistent with four important principles: value should be proportional to a therapy’s benefit; components of value should matter to framework users (patients and payers); attribute weights should reflect user preferences; and value estimates used to inform therapy prices should reflect per-person benefit. Results: All three frameworks can aid decision making by elucidating factors not explicitly addressed by conventional evaluation techniques (in particular, cost-effectiveness analyses). Our case studies identified four challenges: 1) value is not always proportional to benefit; 2) value reflects factors that may not be relevant to framework users (patients or payers); 3) attribute weights do not necessarily reflect user preferences or relate to value in ways that are transparent; and 4) value does not reflect per-person benefit. Conclusions: Although the value frameworks we reviewed capture value in a way that is important to various audiences, they are not always logical or consistent. Because these frameworks may have a growing influence on therapy access, it is imperative that analytic challenges be further explored. Keywords: cost-effectiveness analysis, healthcare costs, oncology treatments, value frameworks.

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The influence of time horizon on results of cost-effectiveness analyses

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Center for the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, Boston, MA, USA

ABSTRACT

Background: Debates persist on the appropriate time horizon from a payer’s perspective and how the time horizon in cost-effectiveness analysis (CEA) influences the value assessment.

Methods: We systematically reviewed the Tufts Medical Center CEA Registry and identified US-based studies that used a payer perspective from 2005–2014. We classified the identified CEAs as short-term (time horizon ≤ 5 years) and long-term (> 5 years), and examined associations between study characteristics and the specified time horizon. We also developed case studies with selected interventions to further explore the relationship between time horizon and projected costs, benefits, and incremental cost-effectiveness ratios (ICER).

Results: Among 782 identified studies that met our inclusion criteria, 552 studies (71%) utilized a long-term time horizon while 198 studies (25%) used a short-term horizon. Among studies that employed multiple time horizons, the extension of the time horizon yielded more favorable ICERs in 19 cases and less favorable ICERs in 4 cases. Case studies showed the use of a longer time horizon also yielded more favorable ICERs.

Conclusion: The assumed time horizon in CEAs can substantially influence the value assessment of medical interventions. To capture all consequences, we encourage the use of time horizons that extend sufficiently into the future.

ARTICLE HISTORY
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KEYWORDS
Time horizon; cost-effectiveness analysis; systematic review; health technology assessment; value assessment
Next Up

Multi-Criteria Decision Analysis (MCDA)

• Technique to include and quantify elements of value not typically included and difficult to quantify

• Also complex, controversial, nascent
## Similarities and Differences

<table>
<thead>
<tr>
<th>Feature</th>
<th>HECOR/Pharma</th>
<th>Actuarial Science/Health Ins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customers</td>
<td>Sick patients, their caregivers, families</td>
<td>Members, sick and well, their caregivers, families Employers, Government</td>
</tr>
<tr>
<td>Business model</td>
<td>Research/biologic product</td>
<td>Financial product</td>
</tr>
<tr>
<td>Nature of risks</td>
<td>Biologic, regulatory, financial</td>
<td>Financial</td>
</tr>
<tr>
<td>Research questions</td>
<td>Causation</td>
<td>Correlation</td>
</tr>
<tr>
<td>Pricing</td>
<td>Treatments, proprietary</td>
<td>Premiums, proprietary</td>
</tr>
<tr>
<td>Models</td>
<td>CEA, Costs per QALY*</td>
<td>Medical loss ratio</td>
</tr>
<tr>
<td>Regulation</td>
<td>FDA, CMS, States</td>
<td>FTC, CMS, States</td>
</tr>
<tr>
<td>Skillset</td>
<td>Clinical, economic, statistical, behavioral, uncertainty</td>
<td>Financial, statistical, behavioral, uncertainty</td>
</tr>
<tr>
<td>Focus</td>
<td>Therapeutic areas</td>
<td>Book of business</td>
</tr>
<tr>
<td>Analytic timeframe</td>
<td>Medium/Long-term</td>
<td>Short/Medium-term</td>
</tr>
<tr>
<td>Data sources</td>
<td>RCTs, claims, EHRs, surveys</td>
<td>Claims, EHRs</td>
</tr>
<tr>
<td>Timeframe</td>
<td>10+ years</td>
<td>1-3 years</td>
</tr>
<tr>
<td>Scope</td>
<td>Health care system, society</td>
<td>Health care system</td>
</tr>
</tbody>
</table>

* Controversial, not generally accepted
Collaborating to Improve Outcomes

• Include patient/member perspectives in value
• Ideas for reconciling different timeframes
• Research on coverage policy outcomes
• Eliminating waste in health care
• Benefit design innovation
• Generics
• Enabling value-based contracting
• Regulatory reforms
• Channel discounts/rebates
• Trade agreements (international)
Agenda

- Actuarial/Pharmacy Modeling
- Episode Treatment Groups
- Sample Payer Addressable Burden
- Sample Formulary Design Model
- Sample Return on Investment Model
Agenda

- Actuarial/Pharmacy Modeling
  - Episode Treatment Groups
  - Sample Payer Addressable Burden
  - Sample Formulary Design Model
  - Sample Return on Investment Model
Optum actuaries use the process flow below as the backbone for initiatives designed to provide insight to payer modeling of financial risks and opportunities. Modeling initiatives focus on specific pharmaceutical products and/or diseases and can be implemented step-by-step or as one comprehensive, continuous project.
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Episode Treatment Groups

Episode Treatment Groups (ETGs) provide a condition classification methodology that combines related services into medically relevant and distinct units describing complete episodes of care and associated costs.

- Each cluster has only one anchor record
- Each claim line can be assigned to one, and only one, episode of care

- This project used the Symmetry® Episode Treatment Groups® (ETGs), which is the leading episode grouper in the marketplace and is licensed by more than 300 health care organizations, serving more than half of the insured US population.
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- Actuarial/Pharmacy Modeling
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- Sample Return on Investment Model
Sample Population Demographics

1Population – This is based on all members in our database
Allowed Cost Per Episode
Primary Condition Only

Sample Payer Addressable Burden

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>3 year Avg</th>
<th>Chronic ETGs of Entire Population</th>
<th>All ETGs of Entire Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,400</td>
<td>$1,600</td>
<td>$1,800</td>
<td>$1,600</td>
<td>$1,800</td>
<td>$1,400</td>
</tr>
</tbody>
</table>

- Pharmacy
- Surgery
- Management
- Facility
- Ancillary

68.4%
Total PAB – Allowed Cost per Episode
Primary Condition + Associated Comorbidities

- Pharmacy was the largest contributor to the PAB averaging $1,598 (40.3%); this compares to $1,132 for the Main Condition only which represented 68.4% of the total episode cost
- Per episode cost for ancillary, facility, and management were between $708 and $721
# Primary Condition
Per Episode and PMPM Allowed Costs

<table>
<thead>
<tr>
<th>Segment</th>
<th>Year</th>
<th>Total Cost per Episode</th>
<th>Total Cost PMPM</th>
<th>Total Cost per Episode</th>
<th>Total Cost PMPM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commercial</strong></td>
<td>Year 1</td>
<td>$1,627</td>
<td>$7.45</td>
<td>$3,654</td>
<td>$16.73</td>
</tr>
<tr>
<td></td>
<td>Year 2</td>
<td>$1,670</td>
<td>$8.32</td>
<td>$3,707</td>
<td>$18.46</td>
</tr>
<tr>
<td></td>
<td>Year 3</td>
<td>$1,931</td>
<td>$9.50</td>
<td>$3,943</td>
<td>$19.39</td>
</tr>
<tr>
<td></td>
<td>Average</td>
<td>$1,744</td>
<td>$8.41</td>
<td>$3,770</td>
<td>$18.19</td>
</tr>
<tr>
<td><strong>Medicare</strong></td>
<td>Year 1</td>
<td>$1,487</td>
<td>$45.87</td>
<td>$4,175</td>
<td>$128.79</td>
</tr>
<tr>
<td></td>
<td>Year 2</td>
<td>$1,467</td>
<td>$37.72</td>
<td>$4,083</td>
<td>$105.00</td>
</tr>
<tr>
<td></td>
<td>Year 3</td>
<td>$1,695</td>
<td>$42.11</td>
<td>$4,314</td>
<td>$107.15</td>
</tr>
<tr>
<td></td>
<td>Average</td>
<td>$1,552</td>
<td>$41.44</td>
<td>$4,190</td>
<td>$111.89</td>
</tr>
</tbody>
</table>
Comparison of Comorbidities Costs with and without the Primary Condition

Across the sample 4 comorbidities below, 26% of the episodes are with patients who also have the Primary Condition (PC). On average, per episode cost for comorbidities with the Primary Condition are 10.8% higher than without the Primary Condition.

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Percent of Total Episodes</th>
<th>Average Cost per Episode</th>
<th>Average Cost w/ PC over w/o PC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemic Heart Disease</td>
<td>31%</td>
<td>69%</td>
<td>$4,940</td>
</tr>
<tr>
<td>Hypertension</td>
<td>24%</td>
<td>76%</td>
<td>663</td>
</tr>
<tr>
<td>Stroke/Cerebr Dis</td>
<td>27%</td>
<td>73%</td>
<td>5,034</td>
</tr>
<tr>
<td>Chronic Renal Failure</td>
<td>40%</td>
<td>60%</td>
<td>4,454</td>
</tr>
<tr>
<td>Total</td>
<td>26%</td>
<td>74%</td>
<td>1,872</td>
</tr>
</tbody>
</table>
Agenda

- Actuarial/Pharmacy Modeling
- Episode Treatment Groups
- Sample Payer Addressable Burden
- Sample Formulary Design Model
- Sample Return on Investment Model
Overview of Layout

Model Navigation Buttons

Model Flow

1) Apply plan-specific inputs to flexible model
2) Review Results summarized as
   • High level annual net plan PMPM cost projections
   • Drug-specific price and utilization projections
3) Save different input/result scenarios
4) Review Dictionary tab for terminology definitions
5) Review Reference tab for assumption resources
FDM Key Assumptions

1. Current & New Drugs in Therapeutic Class
2. Launch Year of Drug X and Other New Drugs
3. Trends
   - Utilization, Prevalence, Unit Cost
4. Anticipated % of New Members to Use Drug X
5. Utilization Management Impacts
   - Step Edits, Prior Authorization, & Formulary Tier
6. Pricing Assumptions
   - Price of New Drugs
   - Patent Accelerations
   - Projected Rebates
7. Member Cost Share
8. Any key assumptions that may be therapeutic specific
FDM Outputs

### Commercial Results

<table>
<thead>
<tr>
<th>Year</th>
<th>Utilization Mgmt Drug X</th>
<th>Rebates Drug X</th>
<th>Rebates Competitors</th>
<th>Market Share Drug X</th>
<th>Market Share Competitors</th>
<th>Plan Net Cost PMPM Drug X</th>
<th>Plan Net Cost PMPM Competitors</th>
<th>Plan Net Cost PMPM Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>Step Edits, Not 1st Line</td>
<td>10%</td>
<td>11%</td>
<td>0.2%</td>
<td>99.8%</td>
<td>$0.01</td>
<td>$8.76</td>
<td>$8.77</td>
</tr>
<tr>
<td>2018</td>
<td>Step Edits, Not 1st Line</td>
<td>11%</td>
<td>12%</td>
<td>0.3%</td>
<td>99.7%</td>
<td>$0.02</td>
<td>$10.43</td>
<td>$10.45</td>
</tr>
<tr>
<td>2019</td>
<td>Step Edits, Not 1st Line</td>
<td>12%</td>
<td>14%</td>
<td>0.4%</td>
<td>99.6%</td>
<td>$0.03</td>
<td>$12.46</td>
<td>$12.49</td>
</tr>
</tbody>
</table>

### Drug X vs Competitors

1. Utilization Management Programs
2. Annual Projected Rebates
3. Annual Projected Market Share
4. Annual Plan Net Cost PMPM
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ROI Model Population Subsets

A return on investment (ROI) model is Excel-based and may include the following population cuts:

1) Insurance Type (Commercial vs MAPD)
2) ASO Indicator (ASO vs Fully Insured)
3) Region (West, Central, East, Other)
4) Age Band (<19, 19-64, 65+)
5) Disease State (optional; outlines different subsets of the primary condition)
ROI Model Financial Inputs/Variations

1) Cost Trend
   • Applied to project annual costs

2) Interest Rate
   • Used to determine the net present value of potential savings

3) Churn Rate
   • Simulates the portion of the initial population that will stay with the plan each year

4) Initial Investment
   • Anticipated contract costs/initial plan investments

5) Medical Offset
   • Potential cost savings by: Primary Diagnosis Costs, Total Patient Costs, or Subset Costs (i.e. Rx Only, IP, OP, ER, DME)

6) Risk Adjustment
   • Applied to cost estimates to account for riskiness of the population
ROI Model Outputs

1) Net Present Value of 5 Year Aggregate Savings Projection

2) Other applicable population comparison measures

3) Detailed output with line by line annual projected investments and savings
Questions?